TRANSMITTAL OF APPEAL BRIEF (Large Entity)

Docket No. 66376-252-7

In Re Application Of: **BERGER, Hans et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/854,560	5/15/2001	O'Connor, G. J.	25269	3627	8137

Invention: **DEVICE AND METHOD FOR MGMT. OF OPERATING MATERIALS AND/OR SUPPLIES OF AN ANALYZER OR ANALYZING SYSTEM**

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Dated: **March 14, 2008**

RICHARD H. TUSHIN, Reg.#27,297

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66376-252-7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	PATENT
	)	
Hans BERGER et al.	)	GROUP: 3627
	)	
Serial No.: 09/854,560	)	EXAMINER: O'CONNOR, G. J.
	)	
Filed: May 15, 2001	)	CUSTOMER NO.: 25269
	)	
DEVICE AND METHOD FOR MANAGEMENT OF OPERATING MATERIALS AND/OR SUPPLIES OF AN ANALYZER OR ANALYZING SYSTEM	)	CONFIRMATION NO.: 8137

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APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

March 14, 2008

Sir:

1. Real Party In Interest

The real party in interest to this appeal is Roche Diagnostics Corporation of 9115 Hague Road, Indianapolis, Indiana 46250.

2. Related Appeals and Interferences

There are no other known appeals or interferences which would have a bearing on, or be influenced by, the present appeal.

3. Status of Claims

Claims 1-32 were presented to the examiner for consideration during the prosecution of this application. Claims 1-18 and 31 are on appeal and are reproduced in the Claims Appendix. Claims 19-30 and 32 have been canceled.

4. Status of Amendments

No amendments have been filed subsequent to the issuance of the final Office Action of September 27, 2007.

5. Summary of Claimed Subject Matter

In one embodiment (claim 1) the present invention is directed to a method for the automation of the management of required operating materials and/or supplies of an analyzer or analyzing system used to determine a parameter or a parameter group of a sample used in medical, environmental or food technology, the method steps including (see specification at page 3, line 24 to page 4, line 12):

a) automatically detecting and recording said types and maximum useful lives of said required operating materials, and said types, expiry dates and quantities of said required supplies,

(b) entering a desired frequency of analysis, or automatic calculation of an estimated frequency of analysis from past frequencies of use of said analyzer or analyzing system,

(c) automatically calculating an amount of said operating materials and/or supplies required per unit of time, based on data obtained in steps (a) and (b),

(d) determining an optimum point in time for ordering more of said required operating materials and/or supplies, taking into account the maximum useful lives of said required operating materials, the expiry dates and quantities of said required supplies, and

(e) automatically ordering said operating materials and/or supplies via remote data transmission.

The required operating materials include sensors, sensor cartridges, tubes, seals and software components and the required supplies include cleaning media, quality control media, calibrating media, and ink cartridges (see specification at page 1, lines 14-25 and page 3, lines 15-19).

As defined in claim 10, the data in steps (a) and (b) can be used to calculate service and maintenance intervals, and respective service and maintenance jobs can be requested or ordered via the automatic remote data transmission (see specification at page 7, lines 11-15).

As defined in claim 13, error messages arriving from hardware or software components of the analyzer can be recorded, and respective service and maintenance jobs requested or ordered via the automatic remote data transmission (see specification at page 7, lines 21-25).

As defined in claim 31, in step (e) ordering is proposed by the analyzer and confirmed by a user, or is effected fully automatically by the analyzer after a corresponding function has been activated once (see specification at page 6, lines 22-25).

6. Grounds of Rejection to be Reviewed

The examiner has rejected claims 1-4 and 31 under 35 U.S.C. 103(a) as being unpatentable over Lobiondo et al. (U.S. Patent 5,305,199) in view of Namisniak et al. (U.S. Patent No. 5,711,160), and he has rejected claims 5-18 under 35 U.S.C. 103(a) as being

unpatentable over Lobiondo et al. in view of Namisniak et al. and Sano et al. (U.S. Patent No. 5,415,840). The issues to be decided are whether these rejections are proper.

7. Arguments

A. Rejection of Claims 1-4 and 31

The examiner has rejected claims 1-4 and 31 under 35 U.S.C. 103 (a) as being unpatentable over Lobiondo et al. in view of Namisniak et al.

Lobiondo et al. describe a consumable supplies monitoring/ordering system for reprographic equipment, e.g., for an ink jet printer. The consumable supplies which are administered in the system are, *e.g.*, toners, inks and paper sheets for a plurality of such printers communicating via an inventory tracking system. If at least one of the consumable materials reaches a projected reordering point, information is given via a user interface. An operator can then send his orders to a remote order site. That means the system of Lobiondo et al. is only based on quantity information of the needed consumable supplies.

Such a system as described in LoBiondo et al. will not be sufficient for analyzers or analyzing systems in the medical, environmental or food technologies because for at least some of the required supplies (e.g., calibrating and quality control media of the analyzer) not only quantity information is important, but also particulars with respect to their types and expiry data (step (a) of claim 1). Further, also operating materials

(such as electrochemical or optochemical sensors of the analyzer) are recorded with respect of their maximum useful life in step (a) of claim 1.

As described in the present application (page 4, last paragraph), automatic recordation of data after insertion of new sensor cartridges or other supplies is effected by means of a bar code reader or a transponder system, where a memory chip is provided on or in each sensor cartridge or each supply tank. The memory chip, for instance at the container for the calibrating or quality control media, can be used for storing the current filling level (see also bar code reader 5 and transponder 6 of container 4 or BG and EL modules of inventive variant in Fig. 1).

There is no disclosure or suggestion in LoBiondo et al. regarding automatic recording of the maximum useful life of hardware components of the printer or of recording expiry data of any supplies or operating materials!

With respect to step (b) of claim 1 of the present application, it is sufficient to enter the desired frequency of analysis once by an operator (for initializing a new analyzing system), then the frequency of analysis can be calculated automatically by the analyzer based on data collected in previous periods of use (see paragraph bridging pages 4 and 5). LoBiondo et al. do not show a step of calculating a frequency of analysis.

Further, Lobiondo et al. do not disclose step (c) of claim 1, as the calculation therein is only based on quantity data (see Fig. 1, e.g., counters 24 for determining number of paper sheets remaining). The calculation in the inventive system is also based on expiry dates of

supplies and on maximum useful life of, *e.g.,* sensors and so on. That means that even if the calculated quantity of, *e.g.,* a calibrating solution will be sufficient, the expiry date could be lapsed and thus will cause an automated ordering procedure according step (e) of claim 1.

Namisniak et al. disclose a method and tracking system for ensuring the consumption of perishable food items before a useful storage lifetime for the items has elapsed. There is no mention of the applicability of the invention to reprographic equipment (as in Lobiondo et al.).

The examiner agrees that Lobiondo et al. do not explicitly disclose an automatic detecting and recording of useful lives (see point (a) of applicants' claim 1*:* automatically detecting and recording said types and maximum useful lives of said required operating materials, and said types, expiry dates and quantities of said required supplies). However, the examiner refers to col. 6, lines 10 to 58, of Namisniak and argues that the missing features can be found in this reference:

> The display shows elapsed time in appropriate timing intervals that match the lifetimes entered in the item slot. When the invention is used to track leftovers in a refrigerator, the timing increments are days. For the tracking of frozen or dried food, the increments are weeks or months. A particular base unit might display only one of the possible timing increments. Alternatively, a switch or switches could be provided that would alter the timing increments of individual or of all the displays on a base unit. The more advanced microprocessor version is most flexible and can automatically select and display the appropriate timing interval by selecting an appropriate storage location button marked (R) Refrigerator, (F) Freezer or (P) Pantry).

> A warning signal that shows the status of the elapsed time is provided to alert the user when food items are approaching and/or have reached the end of their estimated storage lifetime. For example, when the food item has been stored within two days of its estimated lifetime, a warning signal would activate. For example, to alert the user, a visually perceptible signal such as a light would illuminate or an audibly perceptible signal such as an alarm or tone would sound. When the actual day of expiration arrived, a different warning signal would activate; for example, the display light would begin to flash or a different sounding alarm or tone would be heard. The warning signals would continue to alert the user until item is removed from the display.
>
> An example might help clarify the functioning of the invention. In a version with multiple numeric displays operating in the "count up" mode (day increments), the timing display will show "0" when it is first activated. Preferably, this display would be next to the lifetime on the item slot. Thus, if the item were salad with a three-day lifetime, the item slot and timing display would look like this: "SALAD 3 0." Each day the timing display is automatically incremented by one day. After 24 hours, the slot and display will read: "SALAD 3 1." After three days, the display will match the lifetime number, indicating that the salad is at the end of its useful lifetime. The goal is to consume the salad before the timing display exceeds the lifetime. When the unit is operating in the "count down" mode, the timing display indicates how many days of useful life are left and would look like this: "SALAD 3 3." Each day the timing display is automatically decremented by one day. After 24 hours, the slot and display will read: "SALAD 3 2." After three days, the display will read "SALAD 3 0" indicating that the salad is at the end of its useful lifetime. The goal is to consume the salad by the time the display reaches 0.

Nowhere in this cited passage, which describes, e.g., tracking leftovers in a refrigerator, is there a disclosure or a hint for automatically detecting and recording the types and maximum useful lives of the required operating materials, and the types, expiry dates and quantities of the required supplies. As can be seen from col. 2, last paragraph, or

from col. 3, lines 53 to 67 of Namisniak, the user manually enters expiration dates of products such as yogurt or milk using an input device such as a keypad.

The feature of automatically detecting and recording ... according point (a) of claim 1 is very important for the invention as shown at paragraph 15 of the description:

> The special advantage of the process proposed by the invention is that the user is relieved in his work and essential parts of the operating materials and supplies management are automated. Automatic recording of data after insertion of new sensor cartridges or other supplies may be effected by means of a bar code reader or transponder system, where a memory chip is provided on or in each sensor cartridge or each supply tank. The memory chip, for instance at the container for the calibrating medium, may also be used for storing the current filling level of the calibrating medium. Besides, it will suffice to enter the desired frequency of analysis once, i.e., analyses planned per unit of time, or the frequency of analysis may be proposed by the analyzer itself on the basis of data collected in previous periods of use, and confirmed by the user. This is followed by an automatic calculation of the operating materials and supplies required per unit of time, and the determination of an optimum ordering point, the location of the analyzer and, as a consequence, the time required for the entire transaction of ordering and delivery being taken into account.

In appellants' method automatically detecting and recording also encompasses all required operating materials, selected from sensors, sensor cartridges, tubes, seals and software components. Namisniak et al. is silent with respect to all of these features.

Neither Lobiondo nor Namisniak et al. disclose feature (c) of claim 1: "automatically calculating an amount of said operating materials and/or supplies required per unit of time, based on data obtained in steps (a) and (b)"

The examiner's comment (paragraph 8 of final Office Action) that appellants' arguments concerning recitations in preambles of the claims (presumably claims 1 and 31) are not accorded patentable weight because the body of the claim does not depend on them for completeness is not relevant as the body of claims 1 and 31 (the active steps recited) do refer back to the respective claim preambles for completeness.

The examiner's prior art rejection against claim 1-4 and 31 should be reversed.

B. Rejection of Claims 5-18

The examiner has rejected claims 5-18 under 35 U.S.C. 103(a) as being unpatentable over Lobiondo et al. in view of Namisniak et al. and Sano.

Sano discloses an analyzer using a test-strip approach where individual test strips are introduced into the sample to be tested, which are contained in test tubes.

Nothing in Sano would overcome the basic deficiencies in the examiner's proposed rejection of claim 1 over Lobiondo et al. in view of Namisniak et al.

B1. Rejection of Claim 11

Claim 11 is separately patentable over Lobiondo et al. in view of Namisniak et al. because it recites the additional steps of using the data obtained in steps (a) and (b) of claim 1 to calculate service and maintenance intervals, and respective service and maintenance jobs are requested or ordered via the automatic remote data transmission. Nothing in Lobiondo et al., Namisniak et al. or Sano teach or suggest these steps.

B2. Rejection of Claim 13

Claim 13 is separately patentable over Lobiondo et al in view of Namisniak et al. because it recites the additional steps of recording error messages arriving from hardware or software components of the analyzer, and requesting (or ordering) perspective service and maintenance jobs via the automatic remote data transmission. Nothing in Lobiondo et al., Namisniak et al. or Sano teach or suggest these steps.

8. Conclusions

The examiner's rejections of claims 1-18 and 31 should be reversed and these claims allowed.

The government filing fee should be charged to Deposit Account No. 04-2223.

Respectfully submitted,

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CLAIMS APPENDIX

1. A method for automation of the management of required operating materials and/or supplies of an analyzer or analyzing system used to determine a parameter or a parameter group of a sample used in medical, environmental or food technology, said required operating materials being selected from the group consisting of sensors, sensor cartridges, tubes, seals and software components and tagged as to types and maximum useful lives, and said required supplies being selected from the group consisting of cleaning media, quality control media, calibrating media, and ink cartridges and tagged as to types, expiry dates and quantities, comprising:

(a) automatically detecting and recording said types and maximum useful lives of said required operating materials, and said types, expiry dates and quantities of said required supplies,

(b) entering a desired frequency of analysis, or automatic calculation of an estimated frequency of analysis from past frequencies of use of said analyzer or analyzing system,

(c) automatically calculating an amount of said operating materials and/or supplies required per unit of time, based on data obtained in steps (a) and (b),

(d) determining an optimum point in time for ordering more of said required operating materials and/or supplies, taking into account

the maximum useful lives of said required operating materials, the expiry dates and quantities of said required supplies, and

(e) automatically ordering said operating materials and/or supplies via remote data transmission.

2. A method according to claim 1, wherein said automated ordering in step (e) is conducted via an internet connection.

3. A method according to claim 1, wherein a unit for remote data transmission is used to provide an internet portal for information on products, software, service maintenance, and use, in the fields of medical, environmental and food technology.

4. A method according to claim 3, wherein said information on products, software, service, maintenance, and use, is updated each time an automatic order is placed according to step (e).

5. A method according to claim 1, wherein in step (a) said data of at least one operating material of a group consisting of electrochemical and optochemical sensors of said analyzer, and said data of at least one supply material of a group consisting of washing, calibrating and quality control media required for cleaning, calibration and quality control of said sensors is recorded.

6. A method according to claim 1, wherein for calculation of said operating materials and supplies required per unit of time according to step (c) a desired range or desired availability of said analyzer is entered.

7. A method according to claim 1, wherein automatic ordering of operating materials and supplies either is proposed by said analyzer and

confirmed by an user or is effected fully automatically by said analyzer after a corresponding function has been activated once.

8. A method according to claim 1, wherein subsequent to said automated ordering of said operating materials and supplies according to step (e) a confirmation of delivery is waited for and, if delivery is delayed, a warning is displayed on said analyzer.

9. A method according to claim 8, wherein in situations of delayed delivery of said operating materials and supplies calibration and quality control cycles of said analyzer are correspondingly extended.

10. A method according to claim 8, wherein in situations of delayed delivery of said operating materials and supplies calibration and quality control cycles of said analyzer are switched over to an emergency or economy program.

11. A method according to claim 1, wherein said data obtained in steps (a) and (b) are used to calculate service and maintenance intervals, and respective service and maintenance jobs are requested or ordered via said automatic remote data transmission.

12. A method according to claim 11, wherein said service and maintenance jobs are requested via an internet connection.

13. A method according to claim 1, wherein error messages arriving from hardware or software components of said analyzer are recorded, and respective service and maintenance jobs are requested or ordered via said automatic remote data transmission.

14. A method according to claim 13, wherein said service and maintenance jobs are requested via an internet connection.

15. A method according to claim 5, wherein an automatic order is initiated according to step (e) in response to a negative result returned by a calibrating or quality control step of said analyzer.

16. A method according to claim 2, wherein a user is offered a help function via said internet connection, as well as access to user groups, a user center, and electronic information media.

17. A method according to claim 2, wherein said internet connection is used for remote repair of hardware or software components of said analyzer.

18. A method according to claim 1, wherein said data collected automatically by said analyzer in steps (a) to (c) are used to analyze consumer behavior and/or calculate effective costs for each analysis, and wherein demand-optimized analyzers or analyzing systems as well as cost-optimized service and maintenance packages are offered on the basis of this information.

19.-30. **(Canceled).**

31. An automation process for the management of required operating materials and supplies of an analyzer or analyzing system used to determine a parameter or a parameter group of a sample used in medical, environmental or food technology, said required operating materials being selected from the group consisting of sensors, sensor cartridges, tubes, seals and software components and tagged as to types

and maximum useful lives, and said required supplies being selected from the group consisting of cleaning media, quality control media, calibrating media, and ink cartridges and tagged as to types, expiry dates and quantities, comprising:

(a) automatically detecting and recording said types and maximum useful lives of said required operating materials and said types, expiry dates and quantities of said required supplies,

(b) entering a desired frequency of analysis, or automatic calculation of an estimated frequency of analysis from past frequencies of use of said analyzer or analyzing system,

(c) automatically calculating an amount of said operating materials and supplies required per unit of time, based on data obtained in steps (a) and (b),

(d) determining an optimum point in time for ordering more of said required operating materials and supplies, taking into account the maximum useful lives of said required operating material, the expiry dates and quantities of said required supplies, and

(e) automatically ordering said operating materials and supplies via a device for remote data transmission, where the ordering is proposed by the analyzer and confirmed by a user, or is effected fully automatically by the analyzer after a corresponding function has been activated once.

32. **(Canceled)**.

EVIDENCE APPENDIX

N/A

RELATED PROCEEDINGS APPENDIX

N/A